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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,073	04/13/2004	Michael G. Lowery	7350.US.O1	3980
23492	7590	03/17/2009		
PAUL D. YASGER ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			EXAMINER BERHANU, ETSUB D	
			ART UNIT 3768	PAPER NUMBER
			NOTIFICATION DATE 03/17/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/823,073	Applicant(s) LOWERY, MICHAEL G.	
	Examiner ETSUB D. BERHANU	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/5/04 11/14/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claims 1-13 are objected to because of the following informalities: the first “of” term in line 1 of claim 1 should be deleted; the term “agents” in line 7 of claim 11 should be amended to read - - agent - -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the layer of coupling agent is capable of being on at least one major surface of the backing, as recited in claim 1, when a substrate layer is interposed between the backing layer and the layer of the coupling agent, as recited in claim 8. Regarding claims 11-13, method step a) of claim 11 provides the article of claim 1, but step b) does not seem to require that the article be used to do the application of the coupling agent. It is suggested that Applicant positively recite the relationship between the article and the rest of the method steps of claims 11-13.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-3 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Delonzor et al.'136 (cited by Applicant).

Figure 1 of Delonzor et al.'136 discloses an article for applying a coupling agent to the surface of a tissue, the article comprising: a non-permeable membrane 12, a substrate layer 14 and a layer of coupling agent 15, wherein the substrate layer either comprises a fibrous material or a non-fibrous material (the adhesive used to adhere the substrate layer to the backing layer is a non-fibrous material) and the coupling agent comprises mineral oil (see ABSTRACT, description of Figure 1 and col. 3, lines 40-46). Figure 5 discloses an embodiment wherein the coupling agent layer is on at least one major surface of the backing. Delonzor et al.'136 further discloses a method of measuring oxygenated hemoglobin levels in blood, the method comprising providing the article discussed above, applying coupling agent to the surface of tissue, bringing an emitter and detector in contact with the tissue and performing a non-invasive determination of oxygenated hemoglobin through reflectance measurements (col. 1 – col. 3).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delonzor et al.'136.

Delonzor et al.'136 discloses all the elements of the current invention, as discussed in paragraph 5 above, except for the size of the layer of coupling agent and the size of the backing. Regarding claims 4-7, as the Applicant has failed to provide criticality or unexpected results for the values of sizes recited in

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claims 4-7, it would have been within the skill of the art, through due experimentation, to realize an optimum thickness for the coupling agent layer and an optimum area of the backing, in order to provide the most accurate results.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chance'987 (cited by Applicant) and Warring et al.'777 (cited by Applicant) each disclose an article for applying a coupling agent to the surface of a tissue, the article comprising a backing and a layer of coupling agent on a major surface of the backing, and a method using the article for improving the precision of a non-invasive optical measurement of hemoglobin concentration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

EDB